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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,917	10/04/2004	Peter Muhlradt	03100215AA	4470

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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,917	MUHLRADT ET AL.	
	Examiner	Art Unit	
	ROBERT A. ZEMAN	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5-18-2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 12-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-18-2009 has been entered.

The amendment filed on 5-18-2009 is acknowledged. Claims 6-11 have been canceled. Claims 1-5 and 12-16 are pending and currently under examination.

Declaration

The Declaration filed on 5-18-2009 under 37 C.F.R. 1.132 by Dr. Peter F. Muhlradt has been fully considered.

Claim Rejections Maintained

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 12-16 are rejected under 35 U.S.C. 103(a) as being obvious over Muehlradt (U.S. Patent 6,573,242) for the reasons set forth in the previous Office action in the rejection of claims 1, 2 and 4-16.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicant argues:

1. Muehlradt teaches that MALP-2 is a macrophage stimulant and that, as set forth in the Declaration, agents that stimulate macrophages are not necessarily effective mucosal adjuvants.

2. As set forth in the Declaration the ability of MALP-2 to act as a mucosal adjuvant and action on dendritic cells were not known at the time the reference was available to the public.

3. LPS is known to cause septic shock and as such it is unlikely that the same molecule would be used as an adjuvant.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1 and 3, Muehlradt specifically discloses that S-(2, 3-dihydroxypropyl)-cysteine peptides can be used as a vaccine adjuvant. Given that said S-(2, 3-dihydroxypropyl)-cysteine peptide can be used as a vaccine adjuvant and that the use of mucosal adjuvants is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use the S-(2, 3-dihydroxypropyl)-cysteine peptide of Muehlradt as a mucosal adjuvant (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]). The fact that the skilled artisan would not be assured that the S-(2, 3-dihydroxypropyl)-cysteine peptides would be effective as a mucosal adjuvant would not prevent them from making the attempt.

With regard to Point 2, the ability of stimulate dendritic cells is an inherent characteristic of the S-(2, 3-dihydroxypropyl)-cysteine peptide. Applicant is reminded that the mere recognition of inherent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Thus, although the prior art does not specifically anticipate the claimed functional interactions, it is the combination of the references that would inherently lead to the modification of the immunological properties. Moreover, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

As outlined previously, Muehlradt discloses a S-(2,3-dihydroxypropyl)-cysteine peptide which conforms the structure (I) as set forth in claims 1 and 6 and comprises a peptide with the sequence of SEQ ID NO:3 (see abstract). Muehlradt further discloses that said S-(2, 3-dihydroxypropyl)-cysteine peptide can be used as a vaccine adjuvant (see column 2, lines 6-7).

Muehlradt differs from the instant invention in that he doesn't explicitly disclose the use of said S-(2, 3-dihydroxypropyl)-cysteine peptide as a mucosal adjuvant generally or the recited routes of administration specifically.

Given that Muehlradt discloses that said S-(2, 3-dihydroxypropyl)-cysteine peptide can be used as a vaccine adjuvant and that the use of mucosal adjuvants is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use the S-(2, 3-dihydroxypropyl)-cysteine peptide of Muehlradt as a mucosal adjuvant (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]). Moreover, the specific routes of administration and the types of antigens, carriers etc. set forth in the instant claims were also known in the art and would be equally obvious to the skilled artisan.

The rejection of claims 1-5 and 12-16 under 35 U.S.C. 103(a) as being obvious over Muhlradt et al. (Journal of Experimental Medicine, 1997, Vol. 185 No. 11, pages 1951-1958 – IDS filed on 4-12-2005) is maintained for reasons of record. The cancellation of claims 6-11 has rendered the rejection of those claims moot.

Applicant argues:

1. Muhlradt teaches that MALP-2 is a macrophage stimulant and that, as set forth in the Declaration, agents that stimulate macrophages are not necessarily effective mucosal adjuvants.

2. As set forth in the Declaration the ability of MALP-2 to act as a mucosal adjuvant and action on dendritic cells were not known at the time the reference was available to the public.

3. LPS is known to cause septic shock and as such it is unlikely that the same molecule would be used as an adjuvant.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1 and 3, Muhlradt specifically discloses that S-(2, 3-bisacyloxypropyl) cysteine-peptide can be used as a vaccine adjuvant. Given that said S-(2, 3-bisacyloxypropyl) cysteine-peptide can be used as a vaccine adjuvant and that the use of mucosal adjuvants is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use the S-(2, 3-bisacyloxypropyl) cysteine-peptide of Muhlradt as a mucosal adjuvant (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]). The fact that the skilled artisan would not be assured that the S-(2, 3-bisacyloxypropyl) cysteine-peptides would be effective as a mucosal adjuvant would not prevent them from making the attempt.

With regard to Point 2, the ability of stimulate dendritic cells is an inherent characteristic of the S-(2, 3-bisacyloxypropyl) cysteine-peptide. Applicant is reminded that the mere recognition of inherent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Thus, although the prior art does not specifically anticipate the claimed functional interactions, it is the combination of the references that would inherently lead to the modification of the immunological properties. Moreover, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or

obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

As outlined previously, Muhlradt et al. disclose a macrophage stimulator lipopeptide from *Mycoplasma fermentans* (MALP-2) which is an S-(2, 3-bisacyloxypropyl) cysteine-peptide wherein the peptide has the sequence of SEQ ID NO:3 (see abstract). Muhlradt et al. further disclose that MALP-2 is one of the most potent natural macrophage stimulators besides endotoxins (see abstract).

Muhlradt et al. differs from the instant invention in that he doesn't explicitly disclose the use of MALP-2 as a mucosal adjuvant generally or the recited routes of administration specifically.

Given that Muhlradt discloses that MALP-2 is one of the most potent natural macrophage stimulators besides endotoxins and the fact that the use of endotoxins as mucosal adjuvants is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use the MALP-2 of Muhlradt et al. as a mucosal adjuvant (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]). Moreover, the specific routes of administration and the types of antigens, carriers etc. set forth in the instant claims were also known in the art and would be equally obvious to the skilled artisan.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Said claim recites improper Markush language. As such it is impossible to determine the metes and bounds of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-5 and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 9 of U.S. Patent No. 6,573,242.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to vaccination methods utilizing the same peptide adjuvants.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/
Primary Examiner, Art Unit 1645
July 27, 2009